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| 10/781,403 | 02/18/2004 | Joseph Kevin Gogerty | P06281US01 - PHI 1331 | 1872 |
| 27142 | 7590 | 10/17/2005 | EXAMINER | |
| MCKEE, VOORHEES & SEASE, P.L.C. ATTN: PIONEER HI-BRED 801 GRAND AVENUE, SUITE 3200 DES MOINES, IA 50309-2721 | | | FOX, DAVID T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1638 | |

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/781,403

Applicant(s)

GOGERTY, JOSEPH KEVIN

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/26/05 & 8/8/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11, 12, 17 and 18 is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-16 and 19-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/26/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Applicant's Terminal Disclaimer of 26 May 2005 has obviated double patenting rejection of record. Applicant's remarks of 26 May 2005 have overcome the rejections of claims 7-10 under 35 USC 112, first paragraph, regarding the presence of a single cell from an inbred parent. However, these claims remain rejected under 35 USC 112, first paragraph, regarding the issue of F1 hybrids themselves, as stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of 08 August 2005 resulted in the new grounds of rejection applied below.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claims 19 and 23-24 are indefinite in their recitation of "plant of claim 11... further defined as comprising" which is confusing, as the claimed plant is simultaneously being characterized as being the plant of claim 11, which has a particular and finite genotype, as well as being a plant with an additional transgene or single locus conversion.

Claim 22 is indefinite in its recitation of "yield enhancement" and "improved nutritional quality", since these are relative terms, and no standard of comparison or degree of improvement/enhancement has been recited or identified.

Claims 22 and 30 (newly submitted) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to nematode-resistant corn plants, and to methods for making doubled haploid maize plants. However, no basis has been pointed out for this language, and none is apparent. Accordingly, the claims are directed to NEW MATTER.

Claims 1-10 remain, and new claims 13-16 and 19-30 are, rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 3-4 of the last Office action for claims 1-10, regarding F1 hybrids. New claims 13-16 also encompass F1 hybrids, while new claims 19-30 encompass any plant produced by crossing the exemplified inbred with any uncharacterized second plant for one or more generations.

Claims 1-10 remain, and new claims 13-16 and 19-30 are, rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention, as stated on pages 5-7 of the last Office action for claims 1-10, regarding F1 hybrids.

Regarding new claims 19-30, Murray et al teach that linkage drag is a common phenomenon in corn breeding, and that the equivalent of 10 backcrosses resulted in the retention of 10% of the unwanted donor parent genome, in contrast to the predicted less than 1% (see, e.g., pages 82-84).

Moreover, many "value-added traits" such as the newly claimed yield enhancement and improved nutritional quality of claim 22, are conferred by multiple genes, or quantitatively inherited, wherein such traits are incorporated into a desired genetic background via molecular markers. However, the use of molecular markers in corn breeding, as explicitly claimed in new claim 29, is unpredictable.

Goldman et al teach that the use of molecular markers to facilitate the identification of chromosomal regions associated with quantitatively inherited traits is hampered by the different linkage maps generated when different breeding lines are used as parents (see, e.g., page 909, column 2, top paragraph; paragraph bridging pages 911 and 912; paragraph bridging pages 912 and 913). In addition, inconsistent results were observed regarding the correlation of particular quantitatively inherited traits (see, e.g., Goldman et al, page 910). Furthermore, quantitative traits such as oil or protein content are inversely proportional to kernel size (see, e.g., Goldman et al, page 908, column 1, middle paragraph and column 2, bottom paragraph). Murray et al also teach the unpredictability inherent in molecular marker-assisted breeding, given the

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failure to identify molecular markers which are actually specific for particular cultivars (see, e.g., page 79, second full paragraph).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 (newly submitted) is rejected under 35 U.S.C. 102(b) as being anticipated by each of Kevern (US 5,850,009) and Carlone (US 5,763,755).

The claims are drawn to seeds produced from F1 hybrid plants, i.e. F2 seeds. Such F2 seeds encompass seeds of both parents of the F1 hybrid, including the parent which is not the non-exemplified inbred, due to Mendelian segregation. Accordingly, the claims read on any corn plant of any genotype, including those taught by each of Kevern and Carlone.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claims 1-10 remain, and new claims 11-15 and 17-30 are, free of the prior art, for the reasons stated in the last Office action on page 7 for claims 1-10.

Claims 11-12 and 17-18 are allowed.

Applicant's arguments filed 26 May 2005, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the written description rejection is improper, given the conserved sequence of the exemplified inbred parent which comprises one-half of all of the hybrids' genomes, the deposit of the plant material per *Enzo*, and the disclosure of many hybrids produced with the exemplified inbred as one parent.

The Examiner maintains that there is no correlation between the conserved sequence and function, as required by *Lilly* cited previously, since each hybrid would have a completely different set of morphological traits, influenced by the genetic makeup of the second inbred parent.

Regarding *Enzo*, the Examiner maintains that the court only decided that deposit of an organism may provide adequate written description of the same organism. The court in *Enzo* remanded the case to the lower court for decision on whether the deposit of a single microbial strain provided an adequate written description of mutants of that strain. In the instant case, the deposited strain does not differ from the claimed strain by only one or a few mutant genes. Thus, it is even less likely that the court in *Enzo* would deem F1 hybrids to be adequately described by deposit of one inbred parent which potentially differs from the second parent at every genetic locus.

Regarding the disclosure of several hybrids, the Examiner maintains that no correlation has been demonstrated between structure (gene sequence of one parent inbred) and function (the morphological complement of each divergent F1 hybrid descended from a different second parent).

Applicant urges that the enablement rejection is improper, given the inapplicability of the references cited by the Examiner to support his position.

The Examiner maintains that each reference teaches the general unpredictability inherent in corn breeding, wherein said teachings would indeed be applicable to the production of F1 hybrids by crossing a single inbred first parent with a multitude of non-exemplified second parents.

Applicant's arguments filed 08 August 2005 have been fully considered but they are not persuasive. Applicant urges that all claims should be allowed, based upon the Board Decisions in copending applications owned by a different assignee. The Examiner maintains that each case is decided on its own merits, and that the Board Decisions in the copending applications were unpublished and therefore non-precedential.

Applicant is notified that the IDS of 26 May 2005 merely duplicated those references cited by the Examiner in the last Office action. Applicant is invited to submit another IDS which lists those references cited by the Examiner in the parent application, as attempted on 18 February 2004.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 7, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180- 1638

